ONE HUNDRED EIGHTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON THE JUDICIARY

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September 25, 2003

The Honorable Bill Young
Chairman
Committee on Appropriations
U.S. House of Representatives
H-218 The Capitol
Washington, DC 20515

The Honorable David R. Obey
Ranking Member
Committee on Appropriations
U.S. House of Representatives
1016 Longworth HOB
Washington, DC 20515

The Honorable Frank R. Wolf
Chairman
Subcommittee on Commerce, Justice,
State, and Judiciary
U.S. House of Representatives
H-309 The Capitol
Washington, DC 20515

The Honorable José E. Serrano
Ranking Member
Subcommittee on Commerce, Justice,
State, and Judiciary
U.S. House of Representatives
1016 Longworth HOB
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Dear Chairmen and Ranking Members:

As you proceed with consideration of H.R. 2799, the Commerce-Justice-State-Judiciary appropriations legislation for fiscal year 2004, we are writing to express our concerns with section 801, which limits the ability of the U.S. Patent & Trademark Office ("PTO") to issue certain patents.[1] We understand the provision was designed to prohibit patents from being issued on human beings, but we believe the language is unnecessary, overbroad, and could hinder research on vital medical procedures and life-saving drugs.

At the outset, it appears the amendment was offered without notice to members of the House and was not shared with the Committee on the Judiciary, which is the committee of jurisdiction on patent matters. On issues of such importance as what new technologies will be eligible or not eligible for intellectual property protection, we would hope that the relevant committee would be given an opportunity to review new proposals to determine how they might

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[1]This provision prohibits the PTO from issuing "patents on claims directed to or encompassing a human organism." H.R. 2799, 108th Cong., 1st Sess. § 801 (2003) (as passed by the House).

affect current law and what impact they might have on not only the scientific, research, and development communities but also the investment and venture capital communities.

With respect to the substance of the amendment, the provision's stated intent is to prohibit the patenting of human beings,[2] a practice we believe that existing law already prohibits. The existing prohibition stems from the Constitution, itself, which provides that "[n]either slavery nor involuntary servitude . . . shall exist within the United States."[3] Some scholars interpret this to mean that any patent on a human being would subject that being to the ownership and servitude of the patentee in violation of the Thirteenth Amendment.[4] At the statutory level, the patent law also serves to prohibit patents on humans in that it states that "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[5] It can be argued that no person can "invent or discover" another human, such that a patent on a human could not issue. At the regulatory level, the PTO has issued a rule, that has been upheld by the Federal courts, excluding humans from being patentable subject matter.[6] In short, current constitutional doctrine, Federal law, and agency regulation do that which the amendment sets out to accomplish.

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[2]According to the author of the provision, Rep. Dave Weldon (R-FL), the purpose of this language is to prevent the ownership of human beings "by restricting funds for issuing patents on human embryos, human organisms." 149 CONG. REC. H7274 (daily ed. July 22, 2003) (statement of Rep. Weldon).

[3]U.S. CONST. amend. XIII, § 1.

[4]*See, e.g.*, Alison E. Cantor, *Using the Written Description and Enablement Requirements to Limit Biotechnology Patents*, 14 HARV. J.L. & TECH. 267, 276-77 (2000).

[5]35 U.S.C. § 101 (2003).

[6]Animal Legal Defense Fund v. Quigg, 932 F.2d 920 (Fed. Cir. 1991) (upholding U.S. Patent & Trademark Office decision prohibiting patents on humans). The Patent & Trademark Office rule was stated as: "A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101." Decision of Donald J. Quigg, Assistant Secretary of Commerce & Commissioner of Patents and Trademarks (Apr. 7, 1987), *reprinted in* U.S. PATENT & TRADEMARK OFFICE, 1077 OFF. GAZ. 24 (Apr. 21, 1987).

Furthermore, while it has been argued that the provision is limited to patents on humans,[7] we believe the amendment is drafted so broadly that it would prohibit legitimate patents and research on medical techniques and life-saving drugs. For instance, *in vitro* fertilization assists infertile couples with reproduction and necessarily involves research and patents on methods of developing human embryos and transferring them to human uteruses, such that it is "directed to or encompasses" human organisms. Various methods of *in vitro* fertilization have been patented already, but by preventing patents on human organisms, which is undefined in the legislation, the amendment would deter new developments and investments in this vital and life-giving area of research. Second, human growth hormone research, which is vital for persons afflicted with stunted growth, pertains to determining methods of stimulating production of a hormone that affects normal development, bone growth, and cellular energy use. Patents on methods of formulating such a hormone already have been issued, but new research and patents could be prohibited under the provision because the hormone arguably would be "directed to" a human organism. Another type of treatment, gene therapy, relies upon the introduction of modified DNA into the human body to treat disease (i.e., cancer, cystic fibrosis). New therapies lead to patents on the therapy and methods of administering it, and such patents inevitably are "directed to" human organisms by their nature. It would be unfortunate and tragic if these important forms of scientific research could not continue because of this amendment.

Finally, we would note that the likely goal of the amendment is to avert the actual cloning of human beings, not just to prevent the patenting of human organisms. While we agree with the goal of deterring human cloning, we do not believe that amending the patent laws will discourage those who choose to engage in such immoral research. As the U.S. Supreme Court has noted:

> The grant or denial of patents on micro-organisms is not likely to put an end to genetic research or to its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides.[8]

For these reasons, we urge you to remove section 801 from H.R. 2799 as you proceed to work with the Senate on appropriations legislation for fiscal year 2004. If you have any questions or require further information, please feel free to contact us or our staffs.

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[7]During floor debate on the amendment, Rep. Weldon (R-FL) stated that "[the amendment] has no bearing on stem cell research or patenting genes, it only affects patenting human organisms, human embryos, human fetuses or human beings." 149 CONG. REC. H7274 (daily ed. July 22, 2003).

[8]Diamond v. Chakrabarty, 447 U.S. 303, 317 (1980).

Sincerely,

John Conyers, Jr.
Ranking Member
Committee on the Judiciary

Howard L. Berman
Ranking Member
Subcomm. on Courts, the Internet, and Intellectual Property

cc: The Honorable F. James Sensenbrenner, Jr.
Chairman
U.S. House Committee on the Judiciary

The Honorable Lamar Smith
Chairman
U.S. House Subcomm. on Courts, the Internet, and Intellectual Property